IsoRay, Inc.
Form 10-Q
November 14, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

þQUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2011

or

¨TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 001-33407

ISORAY, INC.
(Exact name of registrant as specified in its charter)

Minnesota	41-1458152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
350 Hills St., Suite 106, Richland, Washington	99354
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (509) 375-1202

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).
Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer”, and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨
Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ¨ No x

Number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date:

Class	Outstanding as of November 7, 2011
Common stock, $0.001 par value	28,985,469

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

	(Unaudited) September 30, 2011	June 30, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,594,545	$2,112,254
Accounts receivable, net of allowance for doubtful accounts of $110,031 and $63,867, respectively	972,429	792,835
Inventory	761,906	749,849
Other receivables	19,364	425,901
Prepaid expenses and other current assets	211,857	141,154
Total current assets	3,560,101	4,221,993
Fixed assets, net of accumulated depreciation and amortization	2,998,900	3,208,911
Restricted cash	180,880	180,809
Other assets, net of accumulated amortization	279,469	277,182
Total assets	$ 7,019,350	$7,888,895
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 548,804	$372,259
Accrued protocol expense	101,537	98,159
Accrued radioactive waste disposal	116,367	108,060
Accrued payroll and related taxes	72,668	125,014
Accrued vacation	79,057	70,706
Total current liabilities	918,433	774,198
Asset retirement obligation	677,192	662,181
Total liabilities	1,595,625	1,436,379
Contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,000,000 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-

Common stock, $.001 par value; 193,000,000 shares authorized; 26,493,118 and 26,443,118 shares issued and outstanding	26,493	26,443
Treasury stock, at cost, 13,200 and 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	51,253,620	51,180,237
Accumulated deficit	(45,848,057)	(44,745,833)
Total shareholders' equity	5,423,725	6,452,516
Total liabilities and shareholders' equity	$ 7,019,350	$7,888,895

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc. and Subsidiaries
Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,	
	2011	2010
Product sales	$ 1,213,417	$ 1,327,127
Cost of product sales	1,147,075	1,111,527
Gross income	66,342	215,600
Operating expenses:		
Research and development expenses	251,314	114,522
Research and development reimbursement	(50,000)	-
Sales and marketing expenses	314,418	373,425
General and administrative expenses	652,927	596,133
Total operating expenses	1,168,659	1,084,080
Operating loss	(1,102,317)	(868,480)
Non-operating income (expense):		
Interest income	187	1,061
Financing and interest expense	(94)	(4,463)
Non-operating (expense) income, net	93	(3,402)
Net loss	(1,102,224)	(871,882)
Preferred stock dividends	(2,658)	(2,658)
Net loss applicable to common shareholders	$ (1,104,882)	$ (874,540)
Basic and diluted loss per share	$ (0.04)	$ (0.04)
Weighted average shares used in computing net loss per share:		
Basic and diluted	26,487,140	23,048,754

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended September 30, 2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,102,224)	$ (871,882)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	216,806	224,528
Amortization of deferred financing costs and other assets	6,714	7,262
Accretion of asset retirement obligation	15,011	13,724
Share-based compensation	33,189	24,592
Changes in operating assets and liabilities:		
Accounts receivable, net	(179,594)	62,923
Inventory	(12,057)	3,089
Other receivables	406,537	(4,227)
Prepaid expenses, other current assets and other assets	(70,703)	(45,405)
Accounts payable and accrued expenses	176,545	22,560
Accrued protocol expense	3,378	(29,698)
Accrued radioactive waste disposal	8,307	12,000
Accrued payroll and related taxes	(52,346)	(61,497)
Accrued vacation	8,351	1,756
Net cash used by operating activities	(542,086)	(640,275)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(6,795)	(1,892)
Additions to other assets	(9,001)	-
Change in restricted cash	(71)	(214)
Net cash used by investing activities	(15,867)	(2,106)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	-	(11,919)
Proceeds from sales of common stock, pursuant to exercise of warrants, net	40,244	-
Net cash provided / (used) by financing activities	40,244	(11,919)
Net decrease in cash and cash equivalents	(517,709)	(654,300)
Cash and cash equivalents, beginning of period	2,112,254	1,678,869
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,594,545	$ 1,024,569

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc.
Notes to the Unaudited Consolidated Financial Statements
For the three months ended September 30, 2011 and 2010

1. Basis of Presentation

The accompanying consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries (IsoRay or the Company). All significant intercompany accounts and transactions have been eliminated in consolidation.

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2011. The financial information is unaudited but reflects all adjustments, consisting only of normal recurring accruals, which are, in the opinion of the Company's management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2011.

Certain amounts in the prior-year financial statements have been reclassified to conform to the current year presentation. These reclassifications had no effect on net loss or shareholders' equity as previously presented.

2. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standards setting bodies that are adopted by us as of the specified effective dates. Unless otherwise discussed, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position, results of operations and cash flows upon adoption.

3. Loss per Share

Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is anti-dilutive. At September 30, 2011 and 2010, the calculation of diluted weighted average shares did not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be anti-dilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2011 and 2010, were as follows:

	September 30,	
	2011	2010
Preferred stock	59,065	59,065
Common stock warrants	3,784,185	3,165,768
Common stock options	2,318,706	2,151,372
Total potential dilutive securities	6.161.956	5,376,205

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4. Inventory

Inventory consisted of the following at September 30, 2011 and June 30, 2011:

	September 30, 2011	June 30, 2011
Raw materials	$ 655,077	$ 625,394
Work in process	94,186	120,180
Finished goods	12,643	4,275
	$ 761,906	$ 749,849

5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2011 and 2010:

	Three months ended September 30,	
	2011	2010
Cost of product sales	$ 12,090	$ 8,470
Research and development expenses	7,630	5,410
Sales and marketing expenses	2,605	3,847
General and administrative expenses	10,864	6,865
Total share-based compensation	$ 33,189	$ 24,592

As of September 30, 2011, total unrecognized compensation expense related to stock-based options was $240,410 and the related weighted-average period over which it is expected to be recognized is approximately 1.09 years.

The Company currently provides stock-based compensation under three equity incentive plans approved by the Board of Directors. Options granted under each of the plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2011 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2011	2,318,706	$ 1.83	6.25	$ 465,690
Vested and expected to vest at September 30, 2011	2,222,772	$ 1.88	6.20	$ 424,031
Vested and exercisable at September 30, 2011	1,882,682	$ 2.06	5.96	$ 364,721

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There were no options granted or exercised during the three months ended September 30, 2011 and 2010, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

6. Contingencies

Royalty Agreement for Invention and Patent Application

A shareholder of the Company previously assigned his rights, title and interest in an invention to IsoRay Products LLC (a predecessor company) in exchange for a royalty equal to 1% of the Gross Profit, as defined in the royalty agreement, from the sale of "seeds" incorporating the technology. The patent and associated royalty obligations were transferred to the Company as part of a merger.

The Company must also pay a royalty of 2% of Gross Sales, as defined in the royalty agreement, for any sub-assignments of the aforesaid patented process to any third parties. The royalty agreement will remain in force until the expiration of the patents on the assigned technology, unless earlier terminated in accordance with the terms of the underlying agreement.

During the three months ended September 30, 2011 and 2010, the Company recorded royalty expenses of $3,914 and $5,743, respectively.

Patent and Know-How Royalty License Agreement

The Company is the holder of an exclusive license to use certain "know-how" developed by one of the founders of a predecessor to the Company and licensed to the Company by the Lawrence Family Trust, a Company shareholder. The terms of this license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty based on Net Factory Sales Price, as defined in the agreement, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and therefore no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this "know-how" in the future.

The licensor of the "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

Wrongful Death Claim

The Company and a former employee have been named as defendants in a wrongful death claim in the State of Indiana as the result of an automobile accident. The suit alleges that the individual died as the result of a medical condition alleged to be the result of injuries sustained in the automobile accident. The claim if upheld at trial is not expected to result in an award of damages that will exceed the available insurance coverage. However, if the court awards exemplary damages then this award may have a financial impact on the Company. Management plans to defend the Company against the claim.

7. Preferred Dividends

As of September 30, 2011, there were dividends on the Series B Preferred Stock outstanding that were cumulative but not declared in the amount of $7,974.

8. Shareholders' Equity

On July 12, 2011, the holder of the Series C warrants issued in the November 2010 offering exercised Series C warrants for 50,000 shares of common stock with an exercise price of $0.81 and a total of $40,244.

On August 1, 2011 as part of a consulting agreement, the Company issued warrants to purchase 15,000 shares of common stock in exchange for shareholder relations consulting services. The warrants were issued to the following individuals in the amounts indicated: warrants to purchase 7,000 shares of common stock to Laurie Roop, warrants to purchase 7,000 shares of common stock to Elwayne Hafen and warrants to purchase 1,000 shares of common stock to John Lefebvre with an exercise price equal to $1.10. These warrants were later cancelled as of October 14, 2011 when this consulting agreement was terminated.

9. Related Party Transaction

During the three months ended September 30, 2011, the Company continued to engage the services of APEX Data Systems, Inc., owned by Dwight Babcock, the Company's Chairman and Chief Executive Officer, to modify and maintain the Company's web interfaced data collection application to aggregate patient data in a controlled environment. The Board of Directors approved the use of the ongoing services of APEX Data Systems with Mr. Babcock recusing himself due to his conflict of interest. The cost recorded during three months ended September 30, 2011 from APEX Data Systems, Inc. to build a web interfaced data collection application was $5,200 for which entries were recorded to fixed assets, net of accumulated depreciation.

10. Subsequent Events

On October 13, 2011, the Company entered into an Underwriting Agreement with WestPark Capital, Inc., as managing underwriter, for a best efforts underwritten registered offering of 2,500,000 shares of the Company's common stock, par value $0.001 per share, at an offering price to the public of $0.92 per share. With every five shares of Common Stock purchased, the purchaser received a warrant to purchase one share of Common Stock at an exercise price of $1.058 with a five year term. Under the terms of the Underwriting Agreement, the Company has also granted the underwriters a 45-day option to sell up to an additional 1,027,173 shares of Common Stock (with warrants to purchase up to an additional 205,435 shares of common stock) to cover over-allotments, if any, at the offering price. The over-allotment option has not been exercised and no warrants have been exercised. The net proceeds to the Company from the sale of the initial 2.5 million shares of Common Stock were approximately $2,089,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-Q contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (“PSLRA”). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under “Risk Factors” under Part II, Item 1A below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2011 that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company’s financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company’s annual report on Form 10-K as filed with the Securities and Exchange Commission on September 28, 2011 are those that depend most heavily on these judgments and estimates. As of September 30, 2011, there had been no material changes to any of the critical accounting policies contained therein. Management continues to estimate that the effective tax rate for the Company is at 0%.

Results of Operations

Three months ended September 30, 2011 compared to three months ended September 30, 2010

Revenues. Total revenues for the three months ended September 30, 2011 decreased 9% as compared to the three months ended September 30, 2010. The overall decrease of 9% was a combination of an 11% decrease in revenue from prostate brachytherapy and partially offset by a 20% increase in revenue directly attributable to other treatments which include the treatment of lung cancer, brain cancer, colorectal cancer, gynecological cancer, and head and neck cancer.

The decrease in revenue during the three months ended September 30, 2011 is attributed to a decrease in prostate brachytherapy purchased by a few key customers. Management believes that this decrease in revenue is a seasonally influenced temporary reduction that is the result of physicians or their case referral sources taking time off in July 2011 as the key customers returned to more typical ordering volumes in August and September 2011.

The other treatments, which include lung cancer, brain cancer, colorectal cancer, gynecological cancer and head and neck cancer treatments, experienced continued growth at a rate of 20% in the three months ended September 30, 2011 compared to the three months ended September 30, 2010. The growth in other revenue is attributed to an increased acceptance of Cesium-131 as a clinically effective treatment method for these additional body sites. The increased acceptance of the Cesium-131 brachytherapy seeds is the result of physicians continuing positive experiences using Cesium-131 in the treatment of these new modalities. As of September 30, 2011, there have been over 100 such treatments at major cancer centers across the United States. All non-prostate treatment revenue represents approximately 10% of revenues during the three months ended September 30, 2011 compared to approximately 7% of revenues in the three months ended September 30, 2010.

Management believes that revenues will recover in prostate therapy as recently added favorable studies should add credibility to generate additional cases and as studies that are underway mature and information about their results is disseminated. The Company is actively sharing the five year data showing the favorable results of Cesium-131 treatment in the prostate with physicians via their sales team while awaiting publications in peer reviewed journals based on this data. This may also enhance interest and sales in non-prostate treatments as new products and applications utilizing similar technologies, and those that are currently under development, are introduced to the market. Management expects other non-prostate revenue will continue to grow as existing treatments and new products under development are accepted into the market.

Key operating factors

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Product Sales (Prostate)	$ 1,096,478	$ 1,229,552	$ (133,074)	(11)%
Product Sales (Other)	$ 116,939	$ 97,575	$ 19,364	20 %
Total product sales	$ 1,213,417	$ 1,327,127	$ (113,710)	(9)%

Cost of product sales. Costs for the three months ended September 30, 2011 increased by $35,548 to $1,147,075 compared to $1,111,527 for the three months ended September 30, 2010. This cost increase was the net result of two operating factors.

The net increase in cost of product sales was created by a temporary increase in the cost of isotope purchased and consumed during the three months ended September 30, 2011. During August 2011, the Company was reliant on a single source for its Cesium-131. The primary supplier underwent scheduled maintenance and took its reactor off-line. As a result, the Company incurred additional costs of isotope of approximately $70,000. Since this vendor did not meet its contractual obligation during this period, the Company has negotiated a future concession which is expected to approximate the cost differential during the three months ending September 30, 2011.

The increase in materials cost was partially offset by a decrease in payroll, benefits and share-based compensation of approximately $39,000. This decrease is the result of continued contributions to research and development projects by production employees and the related cost of that contribution.

Key operating factors

Description	Three months ended, September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Material	$ 499,017	$ 428,575	$ 70,442	16 %
Pre-loading	$ 100,653	$ 95,770	$ 4,883	5 %
Payroll, benefits and share-based compensation	$ 176,600	$ 215,407	$ (38,807)	(18)%
Cost of product sales (Other)	$ 370,805	$ 371,775	$ (970)	0 %
Total cost of product sales	$ 1,147,075	$ 1,111,527	$ 35,548	3 %

Gross income. Gross income decreased by $149,258 to gross income of $66,342 in the three months ended September 30, 2011 from gross income of $215,600 in the three months ended September 30, 2010. The decrease of 69% is attributed primarily to a decrease in sales of $113,710 created by a temporary change in the referral pattern in July of a key customer and a temporary increase in cost of product sales of $35,548 resulting from the use of a U.S. based source of Cesium-131 while the reactors in Russia were offline.

Gross income as a percentage of product sales decreased from approximately 16% for the three months ended September 30, 2010 to approximately 5% for the three months ended September 30, 2011.

Key operating factor

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Gross profit	$ 66,342	$ 215,600	$ (149,258)	(69)%

Gross profit percentage	5	%	16	%

Research and development. Research and development costs have increased in the three months ended September 30, 2011 compared to the three months ended September 30, 2010 by $136,792 or 119%. Research and development costs for the three months ended September 30, 2011 were $251,314 compared to costs for the three months ended September 30, 2010 of $114,522. The research and development increases are attributed to continued efforts on research related to developing treatments applicable to other organs particularly the brain, lung and breast. These increased research and development costs include additional cost related to material and labor utilized in these research activities. The Company expects to continue to incur research and development costs to further develop these new treatments and may initiate new protocols associated with these treatments.

The Company invested approximately $25,000 in other organ research during the three months ended September 30, 2011compared to $2,000 during the three months ended September 30, 2010, an increase of $23,000 or 1,150%. The additional investment related to payroll, benefits and share-based compensation through the shifting of production personnel from an operations expense to support research and development projects was approximately $78,000 increasing from approximately $65,000 during the three months ended September 30, 2010 to approximately $143,000 during the three months ended September 30, 2011. An additional investment of approximately $27,000 was made in protocols in the three months ended September 30, 2011 for a total cost of approximately $38,000 compared to approximately $11,000 for the three months ended September 30, 2010.

The investment in research and development represents 17% of revenues during the three months ended September 30, 2011 as compared to 9% of revenue during the three months ended September 30, 2010. The Company expects to continue to focus on the development of treatments for new modalities in the body and expects to continue to invest in research and development efforts going forward.

Research and development costs were partially offset by reimbursements recorded in the amount of $50,000 recorded in the consolidated statement of operations described as research and development reimbursement. This reimbursement amount represents the amount of cost sharing that was negotiated with the future distributor of the GliaSite Radiation Therapy System. This amount was invoiced and received from the future distributor during the three months ended September 30, 2011 even though the distribution agreement was not executed until October.

Key operating factors

Description	Three months Ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Other organ research	$ 25,143	$ 2,325	$ 22,818	1,150 %
Payroll, benefits and share-based compensation	$ 142,820	$ 65,352	$ 77,468	119 %
Protocol expense	$ 37,789	$ 10,969	$ 26,820	245 %
Research and development (Other)	$ 45,562	$ 35,876	$ 9,686	27 %
Gross research and development	$ 251,314	$ 114,522	$ 136,792	119 %
Research and development cost recovery	$ (50,000)	$ -	$ (50.000)	(100)%
Net research and development cost	$ 201,314	$ 114,522	$ 86,792	76 %

Sales and marketing expenses. Sales and marketing expenses were reduced by 16% in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010. The costs were reduced from $373,425 in the three months ended September 30, 2010 to $314,418 in the three months ended September 30, 2011. The reduction of $59,007 is a result of reductions in consulting and payroll, benefits and share-based compensation. Consulting cost was decreased by approximately $17,000 as the result of a consultant no longer being utilized by the Company and payroll, benefits and share-based compensation was decreased by approximately $48,000 as the result of both a change in the composition of sales force and the length of their tenure with the Company.

Sales and marketing expense represents 26% of revenues during the three months ended September 30, 2011 as compared to 28% of revenue during the three months ended September 30, 2010.

Management believes the staffing level and skill set of the sales organization is appropriate to serve the current market conditions. Expansion of the staff will occur when the current staff does not have the capacity to properly serve the existing customer base while aggressively pursuing new sales opportunities.

Key operating factors

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Consulting	$ (900)	$ 16,500	$ (17,400)	(105)%
Payroll, benefits and share-based compensation	$ 213,031	$ 260,665	$ (47,634)	(18)%
Sales and marketing (Other)	$ 102,287	$ 96,260	$ 6,027	6 %
Total sales and marketing	$ 314,418	$ 373,425	$ (59,007)	(16)%

General and administrative expenses. General and administrative expenses increased by 10% in the three months ended September 30, 2011 as compared to the three months ended September 30, 2010. General and administrative expenses increased $56,794 to $652,927 in the three months ended September 30, 2011 from $596,133 in the three months ended September 30, 2010.

General and administrative expenses represent 54% of revenues during the three months ended September 30, 2011 as compared to 45% of revenue during the three months ended September 30, 2010.

The general and administrative expenses were impacted in three operating functions. Bad debt expense increased by $50,487 or 1,168% resulting from a single customer’s failure to remit payment within the time period required. During the three months ended September 30, 2011, the Company was negotiating various alternative additional equity investments and incurred additional legal costs that were not able to be charged to an equity transaction. The Company incurred additional legal expenses in the amount of $34,214 or an increase of 98% during the three months ended September 30, 2011. Other expense decreased by $41,953 as the Company incurred a non-recurring charge in the three months ended September 30, 2010 as the result of a state tax credit being rescinded as the Company failed to continue to meet the criteria to receive the credit and was obligated to repay the taxing authority for the amount of the credit taken over a two year period.

Key operating factors

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Bad debt expense	$ 46,165	$ (4,322)	$ 50,487	1,168 %
Legal	$ 69,143	$ 34,929	$ 34,214	98 %
Other expense	$ 18,789	$ 60,742	$ (41,953)	(69)%
General and administrative (Other)	$ 518,830	$ 504,784	$ 14,046	3 %
Total general and administrative	$ 652,927	$ 596,133	$ 56,794	10 %

Operating loss. The operating loss for the three months ended September 30, 2011 increased $233,837 from $868,480 for the three months ended September 30, 2010 compared to $1,102,317 for the three months ended September 30, 2011. The operating loss increase of $233,837 or 27% is primarily attributed to the decrease in sales and the increased cost of product sales.

Key operating factor

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Operating loss	$ (1,102,317)	$ (868,480)	$ (233,837)	(27)%

Interest income. Interest income for the three months ended September 30, 2011 was reduced compared to the three months ended September 30, 2010 as a direct result of reduced cash and cash equivalent balances coupled with reduced short-term interest rates.

Key operating factor

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Interest income	$ 187	$ 1,061	$ (874)	(82)%

Financing and interest expense. Financing and interest expense for the three months ended September 30, 2011 decreased compared to the three months ended September 30, 2010 as a direct result of loan facilities being paid off and the related deferred financing costs being fully expensed.

Key operating factors

Description	Three months ended March 31, 2011	Three months ended March 31, 2010	Variance ($)	Variance (%)
Interest expense	$ 94	$ 3,910	$ (3,816)	(98)%
Deferred financing expense	$ -	$ 553	$ (553)	(100)%
Total financing and interest expense	$ 94	$ 4,463	$ 4,369	(98)%

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Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the three months ended September 30, 2011, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used by operating activities is the net loss adjusted for non-cash items and changes in operating assets and liabilities. Management continued to actively manage the cash consumed in operating activities through a combination of cost reductions and operational efficiencies identified in the results of operations that resulted in a reduction in net loss which was then reduced by the non-cash items and changes in operating assets and liabilities for the three months ended September 30, 2011 when compared to the three months ended September 30, 2010. Net cash used by operating expenses was reduced by $98,189 to $542,086 for the three months ended September 30, 2011 compared to $640,275 for the three months ended September 30, 2010.

Key operating factors

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Net loss	$ (1,102,224)	$ (871,882)	$ (230,342)	26 %
Non-cash items	$ 271,720	$ 270,106	$ 1,614	1 %
Non-cash changes in operating assets and liabilities	$ 288,418	$ (38,499)	$ 326,917	849 %
Net cash used by operating activities	$ (542,086)	$ (640,275)	$ 98,189	(15)%

Cash flows from investing activities

Cash used by investing activities increased by $13,761 to $15,867 during the three months ended September 30, 2011 compared to $2,106 for the three months ended September 30, 2010. The cash used to purchase fixed assets is primarily for the routine replacement of equipment. The cash used for additions to other assets is primarily related to extension and maintenance costs for trademarks and patents that the Company is actively pursuing. The amounts recorded to restricted cash in both periods are the accrual of interest earned on certificates of deposit with two financial institutions that are a requirement of the Washington State Department of Health.

Key operating factors

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Purchases of fixed assets	$ (6,795)	$ (1,892)	$ (4,903)	259 %
Additions to other assets	$ (9,001)	$ -	$ (9,001)	(100)%
Change in restricted cash	$ (71)	$ (214)	$ 143	(67)%
Net cash used by investing activities	$ (15,867)	$ (2,106)	$ (13,761)	(653)%

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Cash flows from financing activities

Cash provided by financing activities in the three months ended September 30, 2011 was the result of sales of common stock through the exercise of outstanding warrants. Cash used during the three months ended September 30, 2010 was the result of payments on the single remaining debt facility with Hanford Area Economic Investment Fund (HAEIFC).

Key operating factor

Description	Three months ended September 30, 2011	Three months ended September 30, 2010	Variance ($)	Variance (%)
Principal payments on notes payable HAEIFC	$ -	$ (11,919)	$ (11,919)	(100)%
Proceeds from sale of common stock	$ 40,244	$ -	$ 40,244	100 %
Net cash provided (used) by financing activities	$ 40,244	$ (11,919)	$ 52,163	438 %

Projected Fiscal Year 2012 Liquidity and Capital Resources

At September 30, 2011, the Company held cash and cash equivalents of $1,594,545 as compared to $2,112,254 of cash and cash equivalents at June 30, 2011.

The Company had approximately $3.39 million of cash and cash equivalents and no short-term investments as of November 7. 2011. The Company’s monthly required cash operating expenditures were approximately $181,000 in the three months ended September 30, 2011 which represents a 15% decrease of approximately $32,000 from average monthly cash operating expenditures for the three months ended September 30, 2010 which is primarily a result of non-cash changes in operating assets and liabilities which are a component of the reconciliation of net loss to net cash used by operating activities. Management believes that less than $200,000 will be spent on capital expenditures for fiscal year 2012, however, there is no assurance that unanticipated needs for capital equipment may not arise.

The Company intends to continue its existing protocol studies and to begin new protocol studies on lung cancer treatment using Cesium-131. The Company continues to believe that approximately $100,000 in expense will be incurred during fiscal year 2012 related to protocol expenses for lung cancer, dual therapy prostate protocols and mono therapy prostate protocols.

On October 13, 2011, the Company entered into an Underwriting Agreement with WestPark Capital, Inc., as managing underwriter, for a best efforts underwritten registered offering of 2,500,000 shares of the Company's common stock, par value $0.001 per share, at an offering price to the public of $0.92 per share. With every five shares of Common Stock purchased, the purchaser received a warrant to purchase one share of Common Stock at an exercise price of $1.058 with a five year term. Under the terms of the Underwriting Agreement, the Company has also granted the underwriters a 45-day option to sell up to an additional 1,027,173 shares of Common Stock (with warrants to purchase up to an additional 205,435 shares of common stock) to cover over-allotments, if any, at the offering price. The over-allotment option has not been exercised and no warrants have been exercised. The net proceeds to the Company from the sale of the initial 2.5 million shares of Common Stock were approximately $2,089,000, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. These proceeds are included in the cash and cash equivalent balance at November 7, 2011 of

approximately $3.39 million.

Based on the foregoing assumptions, management believes cash and cash equivalents on hand at November 7, 2011 will be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements through at least the next twelve months.

Management plans to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), expanding into other market applications which initially will include head and neck, colorectal and lung implants while maintaining the Company's focus on cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain increases in its revenue. Sales in the prostate market have not shown the increases necessary to breakeven during the past four fiscal years and decreased during the three months ended September 30, 2011. Management believes that this decrease in the three months ended September 30, 2011 was temporary as the key customer who contributed the majority of the decrease in revenue had substantial reductions in purchase volume during July 2011 but then returned to normal purchase volume in August and September 2011. For the three months ended September 30, 2011, revenue from other treatment modalities has increased 20% when compared to the three months ended September 30, 2010. As management is now focused on expanding into head and neck, colorectal, lung and brain applications of Cesium-131 brachytherapy seeds in addition to the reintroduction of the GliaSite Radiation Therapy System, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it attempts to gain market share.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders. Of course, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds, it may be unable to expand into new applications and may need to curtail operations.

Long-Term Debt

IsoRay no longer has any loan facilities outstanding.

Other Commitments and Contingencies

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company’s product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company’s obligations at its current production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all leasehold improvements.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company has no off-balance sheet arrangements.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, the Company is not required to provide Part I, Item 3 disclosure in this Quarterly Report.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2011. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The Company is continuing the process of developing and implementing the remediation plan to address the material weakness and significant deficiency identified in its Form 10-K for the fiscal year ended June 30, 2011.
This plan is as follows:

- In June 2011, the Company filled the open accounting position to address the segregation of duties..
- The Company plans to continue to enhance staff knowledge through continued training and periodic reviews.

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the consolidated financial statements for the quarter ended September 30, 2011 fairly present in all material respects the financial condition and results of operations for the Company in conformity with U.S generally accepted accounting principles.

PART II - OTHER INFORMATION

ITEM 1A – RISK FACTORS

There have been no material changes for the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2011.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Use of Proceeds from Registered Securities

On October 27, 2009, we filed a registration statement on Form S-3 to register securities up to $15 million in value for future issuance in our capital raising activities. The registration statement became effective on November 13, 2009, and the commission file number assigned to the registration statement is 333-162694.

There was no material change in the use of proceeds from our November 2010 public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) on November 24, 2010. Through September 30, 2011, we had begun to use the net proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) and as further described in the table below, and invested the remaining net proceeds in cash and cash equivalents.

Proceeds used in the three months ended September 30, 2011:		
Purchase and installation of machinery and equipment	$	1,595
Indirect payments to directors and officers for database development		5,200
Direct payments of salaries to directors and officers		221,987
Working capital		288,927
Total proceeds used in the three months ended September 30, 2011	$	517,709

On July 12, 2011, the holder of the Series C warrants issued in the November 2010 offering exercised 50,000 of the Series C warrants in the amount of $40,244 in exchange for 50,000 shares of common stock with an exercise price of $0.81. As of September 30, 2011, none of the proceeds from the warrant exercise had been used.

On August 1, 2011 as part of a consulting agreement, the Company issued warrants to purchase 15,000 shares of common stock in exchange for shareholder relations consulting services. The warrants were issued to the following individuals in the amounts indicated: warrants to purchase 7,000 shares of common stock to Laurie Roop, warrants to purchase 7,000 shares of common stock to Elwayne Hafen and warrants to purchase 1,000 shares of common stock to John Lefebvre with an exercise price equal to $1.10. The warrants were issued pursuant to the exemption from registration provided by §4(2) of the Securities Act of 1933, as amended. These warrants were later cancelled as of October 14, 2011 when this consulting agreement was terminated.

ITEM 6. EXHIBITS

Exhibits:

31.1 Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer

31.2 Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer

32 Section 1350 Certifications

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 14, 2011

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer
(Principal Executive Officer)

By /s/ Brien Ragle
Brien Ragle, Controller
(Principal Financial and Accounting Officer)